

REMARKS

Claims 8 and 11 are currently amended. Support for the amendments can be found throughout the specification, specifically at paragraph [0005]. No new matter has been added. Claims 8-14 are currently pending.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claim 11 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner states that the phrase "said methacrylate" in line 2 lacks antecedent basis and that only a portion of the "said methacrylate" is composed of methacrylate (Office Action page 2). Claim 11 has been amended to correct the claim language. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §103(a)

Malmonge *et al.* in view of Pissis *et al.*

Claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge *et al.* (Artificial Organs 200, 24:174-178) (hereinafter "Malmonge") in view of Pissis *et al.* (Proceedings of the 10th International Symposium on Electrets 1999 p. 561-564) (hereinafter "Pissis"). The Examiner contends that Malmonge teaches all aspects of the present invention with the exception of the incorporation of fibers into the hydrogel, but that this deficiency is satisfied by Pissis (Office Action page 3-4). The Examiner then concludes that it would have been obvious to combine the teachings of the references to produce a HEMA-AA hydrogel with 10% Nylon fibers (dry weight) with an AA content from 1-5% dry weight (Office Action page 4).

Applicants respectfully traverse the rejection. The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103 provide the following possible rationales:

- (A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods or products) in the same way;

(D) Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8th Edition, rev. 6, §2141.

Applicants proceed with the understanding that this rejection conforms to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable

expectation of success.” DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.** [emphasis added]

See MPEP 8th Edition, rev 6, §2143

The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. See MPEP 8th Edition, rev 6, § 2143

In *KSR*, the Supreme Court did not eliminate the teaching, suggestion, or motivation (TSM) test from the determination of obviousness, but rather merely opposed “a formalistic conception of the words teaching, suggestion, and motivation, or ... overemphasis on the importance of published articles and the explicit content of issued patents.” *KSR International Col. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As the Federal Circuit has subsequently explained:

[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis.... The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of *evidence* – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

Ortho-McNeil Pharmaceutical v. Mylan, 2007-1223, *11 (Fed. Cir. Mar. 31, 2008) (emphasis added). Thus, to establish a *prima facie* case of obviousness the Examiner must show *evidence* of teaching, suggestion, or motivation to make the proposed combination of references that arose before the time of invention. Such a showing is required to guard against allegations of obviousness that are actually derived from impermissible hindsight.

In the Office Action, the only alleged teaching, suggestion, or motivation to make the proposed combination of references is that “It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the teachings of Malmonge et al. in view of Pissis et al. to produce HEMA-AA hydrogel with 10% Nylon fibers (dry weight),

such that the AA content was from 1-5% (dry weight)” (Office Action page 4). However, merely rephrasing the basis of rejection provided in *KSR* fails to provide *evidence* that a person having ordinary skill in the art would combine these *particular references*. Without such an explanation, the proposed combination of references constitutes impermissible hindsight.

Malmonge describes a copolymer of HEMA and acrylic acid (AA) as artificial cartilage material. The acrylic acid ionizes into acrylate and Na^+ , resulting in swelling of the HEMA-AA copolymer and improvement of the compressive strength of the cartilage material. The Examples describe the presence of ionized groups in the hydrogel at a concentration of 1.8 and 3.6% (m/m). Unlike the present invention, Malmonge does not teach the presence of relatively large fibres in the polymer gel which provide adequate strength and increased mechanical properties.

Solely in order to promote prosecution, claim 8 has been amended to recite that the length of the fiber is at least a millimeter. Thus, Applicants’ invention solves the problems associated with the preparation of an artificial cartilage material which displays adequate strength and increased mechanical properties. The solution to this problem is the inclusion of fibres with lengths in the order of millimeters to reinforce the hydrogel. This results in a tissue-substituted material with increased strength and durability.

Pissis is directed towards the dielectric and water sorption properties of poly(hydroxyethyl acrylate) (pHEA) gel reinforced with Nylon nanoparticles. (See Title and first sentence of Introduction). There is no teaching or suggestion in Pissis of the use of millimeter or greater sized fibers as this reference never contemplates improving the strength or durability of the gel. At most, Pissis teaches the application of Nylon prepared by the tedious process of cutting, boiling in strong acid, and ultra sonification.

Moreover, paragraph [0013] of the present specification teaches the uptake of the monomer solution by the fiber, followed by polymerization of the monomers. This results in the straight formation of the polymers through the long fibre molecules. The uptake provides robust bonding of the fiber to the polymer gel matrix. This procedure produces improved anchoring and improved strength and durability of the material.

In contrast, the hydrogel taught by Pissis is prepared by the polymerization of a watery suspension of Nylon nanoparticles and a mixture of monomer/crosslinker/initiator. A maximum concentration of 10% of nanoparticles (weight percentage) in the gel can be

obtained before undesired agglomeration begins (See page 561, last sentence). It is clear that there is no uptake of the monomer solution by the nanoparticles. As such, Pissis teaches away from the transverse polymerization of monomer-soaked fibres as described in the present invention where (1) agglomeration is not an issue and (2) a much higher percentage of fibre (10-70% m/m) is added. Thus, one of skill in the art, with knowledge of the problems associated with agglomeration, would have no motivation to adjust the length of the nanoparticles as taught by Malmonge and Pissis. There is no teaching, suggestion, or motivation to do so because the combination teaches away from Applicants' presently claimed invention of a fibre-reinforced hydrogel comprising a concentration of 10-70% (m/m) fibres with a length of at least a millimeter. Withdrawal of the rejection is respectfully requested.

Malmonge *et al.* in view of Pissis *et al.* and Kou *et al.*

Claims 8 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge in view of Pissis and Kou *et al.* (Journal of Controlled Release 1990 12:241-250; hereinafter "Kou"). The Examiner characterizes Malmonge and Pissis as above. The Examiner contends that these two references do not teach the use of methacrylic acid (MA) in the hydrogel. The Examiner states that this deficiency is satisfied by Kou. The Examiner then concludes that it would have been obvious to substitute modified hydrogel of the Malmonge-Pissis combination with that taught by Kou (Office Action page 5).

Applicants respectfully traverse the rejection. As explained in detail above, the combination of Malmonge and Pissis does not result in Applicants' currently claimed invention of a fibre-reinforced hydrogel comprising a concentration of 10-70% (m/m) fibres with a length of at least a millimeter. Kou does not resolve these deficiencies. Kou describes drug release from methacrylate-methacrylic acid polymer hydrogels. There is no teaching or suggestion in Kou of the use of long fibres for the improvement of strength and durability in hydrogel compositions. A person of skill in the art would have no motivation to combine the references because the combination clearly teaches away from Applicants' hydrogel comprising longer fibers. As such, the present invention is not obvious over Malmonge in view of Pissis and Kou. Applicants respectfully request withdrawal of the rejection.

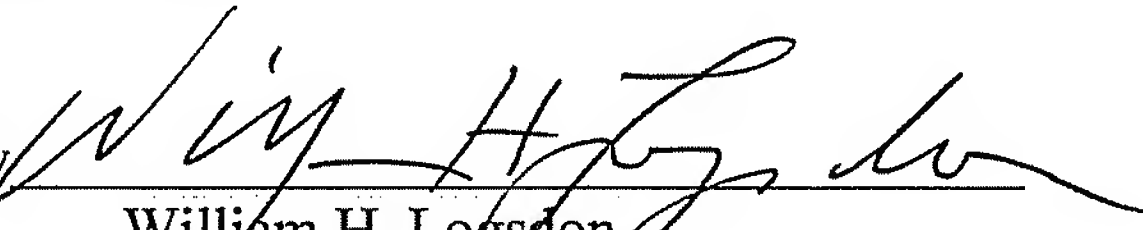
Application No. 10/564,674
Paper Dated: August 28, 2008
In Reply to USPTO Correspondence of March 28, 2008
Attorney Docket No. 0470-060131

Conclusion

Applicants respectfully request reconsideration and submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,

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